

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 15 March 2001 (15.03.01)	
International application No. PCT/SE99/01114	Applicant's or agent's file reference
International filing date (day/month/year) 18 June 1999 (18.06.99)	Priority date (day/month/year)
Applicant ÅKERFELDT, Dan et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
18 January 2001 (18.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

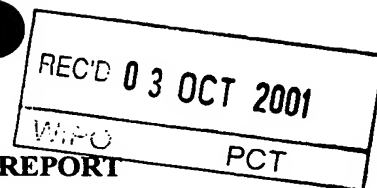
made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Claudio Borton Telephone No.: (41-22) 338.83.38
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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P04871PC/ALi	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE99/01114	International filing date (day/month/year) 18.06.1999	Priority date (day/month/year) -
International Patent Classification (IPC) or national classification and IPC ₇ A 61 B 17/03		
Applicant Radi Medical Systems AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 18.01.2001	Date of completion of this report 13.09.2001
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Anette Hall/EÖ Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01114

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01114

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 9, 10

because:

☒ the said international application, or the said claims Nos. 9, 10

relate to the following subject matter which does not require an international preliminary examination (*specify*):

A method for treatment of the human or animal body by surgery or therapy (Article 34(4)(a)(i) and Rule 67(iv)).

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 8 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 8 searched incompletely: the system according to the claim is not clearly defined because the invention is defined by reference to the sealing device according to claim 7 and by the use of the tool according to claim 1-6. The scope of protection claimed is therefore considered to be speculative and not to be sufficiently supported by the description. The search for the subject matter of claim 8 has only covered the tool according to claim 1-6 and the sealing device according to claim 7.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9, 10

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01114

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☐ not complied with for the following reasons:

1.

Invention 1: Claims 1-6.

Invention 2: Claims 7.

1. Claims 1-6: A tool for closing a wound in the wall of a vessel.

2. Claim 7: A sealing device comprising two plugs.

The inventions are distinct, each from the other because of the following reasons:

Invention 1 can be used without invention 2.

Inventions 1 and 2 lack the same or corresponding special technical features (Rule 13.2).

According to Rule 13(1) PCT, an international application shall relate to one invention or to a group of inventions so linked as to form a single inventive concept.

All searchable claims could be searched without justifying an additional fee.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01114

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-8</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>1-6</u>	YES
	Claims	<u>7,8</u>	NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to an insertion tool, a device and a system for sealing a perforation in the wall of a blood vessel. The insertion tool comprises a gear mechanism and retracting means. The device comprises two rivet portions, which are saw teeth interlocked to clamp the vessel wall about the perforation.

Document US, 5350399, A discloses an intra-arterial occluder, extra-arterial occluder and an insertion tool. The tool is provided to effect sliding of the extra-arterial occluder over the guide and fixation of the extra-arterial occluder to the guide in sealed relation over an opening in body tissue and safe cutting of the guide. Two rivet portions are provided which are saw teeth interlocked to clamp the vessel wall about the perforation.

The tool does not disclose a gear mechanism to create a pushing force forcing the rivets together. The special technical features completely different. Therefore, the tool described in claims 1-6 is not obvious to those skilled in the art.

The claimed invention according to claim 7 differs in that a suture instead of a wire is used to retract the distal rivet. However, suture retracting for intra-arterial occluders are known from US, 5531759, A.

Document US, 5531759, A discloses a system for sealing a percutaneous puncture extending into internally located tissue. The system includes a reinforcing device and a deployment instrument. The device comprises a substantially rigid anchor, a resorbable holding member, a collagen plug,

.../...

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

and a resorbable thin filament connecting the anchor, holding member, and plug in a pulley-like arrangement. The anchor or the plug or both may be formed of a resorbable material having a non-resorbable mesh reinforcement embedded therein. The deployment instrument includes a tubular carrier in which the closure and a tamping member are located. The tamping member is operated to expel the closure so that the anchor is in the interior of the peritoneum and the plug and the holding member are in the puncture tract, with both ends of the filament extending out of the puncture and with the holding member fixedly secured to a portion of the filament adjacent one end. The other end of the filament is then drawn proximally while the tamping is pushed distally to draw the anchor member against the tissue contiguous with the opening.

The skilled person that wants to find an alternative way to close a perforation in the wall of a blood vessel would, faced with the technical problem and the prior art, adapt and modify the alternative solution found and thus arrive at the claimed invention. Consequently, the subject matter of claim 7 lacks inventive step.

Claim 8 does not disclose the technical features of the invention. According to the PCT regulation an invention has to be clearly defined, (see certain observations).

It appears obvious to one skilled in art to apply the features from the a fore-mentioned patents and to arrive at a device according to claim 8. Consequently, the subject matter of claim 8 lacks inventive step.

The claimed invention described in claims 1-8 fulfils the requirement of industrial applicability.

Document US, 5342393, A discloses a device are provided for sealing a perforation in the wall of, for example, a blood vessel. The device is in the form of a two-part closure, which seals the hole by clamping the tissue, surrounding the hole from both the inside and the outside of the vessel. Two rivet portions are provided which are bayonet or screw threadedly interlocked to clamp the vessel wall about the perforation.

This device is not considered to be of particular relevance to the present claimed invention.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01114

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 8 is not clear and concise since the invention is defined by reference to claims 1-7 (Article 6).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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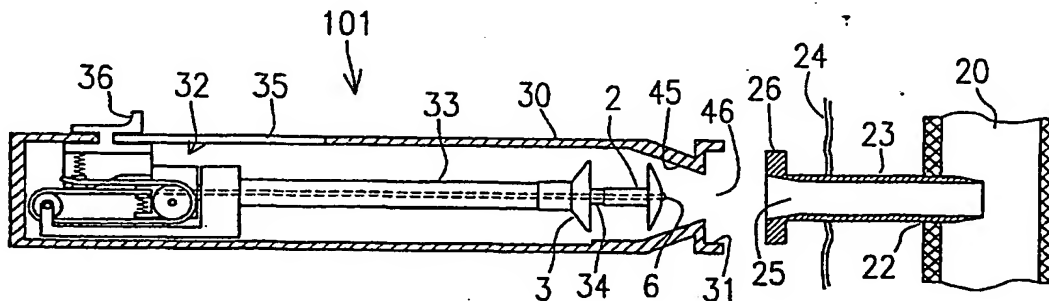
— *With international search report.*

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **ÅKERFELDT, Dan** [SE/SE]; Nyvla, S-755 92 Uppsala (SE). **EGNELÖV, Per** [SE/SE]; Nannas Väg 6, S-754 40 Uppsala (SE).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND**



(57) Abstract: A tool (101) is provided for inserting and mating two plug members (2, 3) of a sealing device (1) for closing a wound in the wall of a vessel by placing the distal plug member (2) of the sealing device inside the vessel and the proximal plug member (3) on the outside of the vessel. The distal plug member is provided with an elongated retracting means (6) extending from the distal plug member. The tool comprises a gear mechanism (32) coupled to the retracting means for converting a movement of the tool in a proximal direction away from the wound (22), when the distal plug member is anchored in the vessel (20), to a pushing movement for moving the proximal plug member in a direction towards the distal plug member in response to a stretching force in the retracting means.

WO 00/78226 A1

TITLE

A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND

SCOPE OF THE INVENTION

- 5 The present invention relates to medical devices, and more specifically to a system for introducing a flexible two-piece wound closure plug in a punctured vessel of a human or animal body.

PRIOR ART

- 10 A sealing device for sealing an arterial puncture is described in US patent 5,350,399 to Erlebacher et al. A first closure member, that is resiliently expandable into a circular disc shape, is positioned within a punctured vessel. A second closure member, also being resiliently expandable into a circular disc shape, is movably fitted onto a guide means being integrally formed with the first closure member. The
- 15 guide means has a saw tooth shape to hold the second closure member. The guide means also acts as a retracting means, i. e. a means for holding the first closure means towards the wound edge, when the first and second closure members are mated.
- 20 A tool for mating said first and second closure members is also disclosed in US patent 5,350,399. Initially, the first closure member and its integrated guide means is pushed into the artery through a percutaneous sheath, normally used for a treatment preceding the closure of the wound. Thus, the tool is not used for insertion of said first member. Then, the guide means of the first closure member is
- 25 passed through the tool, wherein the second closure member is stored in a folded state. Then, the second closure member is pushed out of the tool to be fitted onto the guide means of the first member by operating a trigger of the tool. The force with which the second closure member is mated to the first closure member is visually represented by a force/pressure gauge to avoid too much pressure onto edge
- 30 of the wound. The tool is also used to cut the guide means when the mating is completed.

A similar closure means is disclosed in US patent 5,342,393 to Stack.

- 35 In US patent 5,531,759 to Kensey et al is described a tool for sealing a percutaneous puncture wound in a vessel with a sealing device, the sealing device

including a substantially rigid anchor member for insertion into the vessel and a sealing member to be pressed to the outside of the vessel.

5 **TECHNICAL BACKGROUND**

A puncture wound in a blood vessel typically results from a surgical treatment, such as treatment of a vascular disease, such as atherosclerosis.

10 It is known to close such a wound with a two-piece plug device having a distal member that is inserted in the vessel and a proximal member that is tightened towards the distal member with the vessel wall, i.e. the edge of the wound, clamped between the plug members.

15 Such plugs are described in US patents 5,350,399 and 5,342,393, respectively. In both these inventions, however, the retracting means used to transfer a holding force to the intra-arterial closure member is integrally formed with the intra-arterial closure member and is therefore formed of the same material. This limits the possibilities to manipulate the intra-arterial closure member with a tool.

20 Furthermore, tools presently known are complicated to handle in that they require numerous different grips to perform the closing of the wound.

25 They also require the complete attention from the operator in order to avoid misplacement of the closure members. A misplaced closure plug is difficult to remove, and could even call for surgery.

30 Furthermore, it is essential not to stress the wound too hard in order to avoid rupture of the wound edge. At the same time it is essential to apply a sufficient mating force to the closure members to obtain a leakage-free closing of the wound.

Therefore, there is a need for a method and a system that offers a simple and safe closing of a punctured vessel.

SUMMARY OF THE INVENTION

In a first aspect, it is an object of the present invention to provide a tool for a simple and safe securing of a two-piece wound closing plug around the edge of a puncture wound in a vessel in a human or animal body, thereby obstructing blood leakage through the wound.

This object is achieved with the tool device according to claim 1.

The plug is divided into two plug members prior to insertion in the wound. The tool according to the invention includes a compartment for holding the plug members in a folded shape, means for pushing the plug members out of the plug compartment and a gear mechanism for converting a movement of the tool in a direction from the wound to a movement of the plug pushing means to mate and compress the plug members to form a substantially leakage free wound closure plug.

In a second aspect, it is an object of the present invention to provide a plug for use with the tool according to the invention.

This object is achieved with the sealing device according to claim 7.

The plug according to the invention consists of a distal and a proximal plug member. A central bore through the proximal plug member fits on a cylindrical post centrally protruding from the proximal surface of the distal plug member. The surfaces of the central bore and the cylindrical post, respectively, are provided with projections and corresponding recesses to provide a one-way snap fitting. A central through hole is provided in the cylindrical post of the distal plug member to accommodate a flexible retracting means, such as a biodegradable suture.

Since the retracting means is separate from the distal plug member the distal plug member has an improved flexibility within the artery to adapt to the inner artery wall. At the same time, simplified manufacturing of the distal plug member is obtained.

In a third aspect of the present invention, it is an object to provide a simple and safe method for closing a puncture wound in a vessel.

This object is achieved with the method according to claim 9.

According to the method of the invention, a two-piece plug is inserted into the wound with a specially designed tool. A lever is pushed against the wound to push
5 out the distal plug member of the two-piece plug into the vessel. Then, by simply drawing the tool away from the wound the proximal plug member is pushed out of the tool, the plug members are compressed to form a closure plug that encloses the wound edge in a safe grip and finally the tool is completely removed from the wound to leave only a retracting means (such as a suture) attached to the closure plug. The
10 retracting means is easily cut to a desired length.

BRIEF DESCRIPTION OF ATTACHED DRAWINGS

The present invention shall now be described by way of example and with reference
15 to the attached drawings, wherein:

Fig. 1 is a cross sectional view of an embodiment of the components of a plug device for use with the tool of the invention;

20 Fig. 2 is a cross sectional view of the components of Fig. 1 assembled to form a wound closure plug according to the invention;

Fig. 3 is a cross sectional view of a first embodiment of the tool of the invention, in a state prior to closing a wound.

25

Fig. 4 is a cross sectional view of the embodiment of Fig. 3, when inserting the distal member of a closure plug.

Fig. 5 is a cross sectional view of the embodiment of Fig. 3, when retracting the
30 introducer from the wound.

Fig. 6 is a cross sectional view of the embodiment of Fig. 3, when mating the proximal plug member with the distal plug member being disposed inside the vessel.

35

Fig. 7 is a cross sectional view of the embodiment of Fig. 3, when freeing the plug retracting means from the tool.

5 Fig. 8 is a partly cross sectional view of a second embodiment of the tool of the invention.

Fig. 9 is a detailed view of forces acting on a double gear wheel used in the second embodiment of the tool according to the invention.

10 Fig. 10 is a cross sectional view of the tool according to fig. 8, seen along the line A-A in Fig. 8.

Fig. 11 is a cross sectional view of the tool according to fig. 8, seen along the line B-B in Fig. 8.

15 Fig. 12 is a cross sectional view of the tool according to fig. 8, seen along the line C-C in Fig. 8.

20 Fig. 13 is a cross sectional view of the second embodiment of the tool of the invention, in a state prior to closing a wound.

Fig. 14 is a cross sectional view of the embodiment of Fig. 13, when inserting the distal member of a closure plug.

25 Fig. 15 is a cross sectional view of the embodiment of Fig. 13, when retracting the introducer from the wound.

30 Fig. 16 is a cross sectional view of the embodiment of Fig. 13, when mating the proximal plug member with the distal plug member being disposed inside the vessel.

Fig. 17 is a cross sectional view of the embodiment of Fig. 13, when freeing the plug retracting means from the tool.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

First, a plug being preferred for use with the invention shall be described with reference to Fig. 1 and 2.

5 The plug 1 according to Fig. 1 and 2 includes two generally circular main members: a distal plug member 2 and a proximal plug member 3 being made of a flexible biodegradable material, such as lactide/glycolide polymer or polydioxanone. A foldable generally umbrella-shaped disc portion 51 is formed at the distal end of the distal plug member 2, and a similarly generally umbrella-shaped disc portion 52 is
10 formed at the distal end of the proximal plug member 3. The umbrella-shaped disc portion are formed such that their edges are directed toward each other when the plug members are assembled to form a plug.

The distal plug member 2 is designed to be inserted inside a punctured vessel 20,
15 while the proximal plug member 3 is designed to be provided at the outside of the vessel 20.

The distal plug member 2 is provided with a substantially cylindrical central post 7 protruding in a direction out from the vessel, i.e. in the proximal direction, when
20 the plug member 2 is inserted in the vessel. A central bore 8 extends axially through the post 7.

The proximal plug member 3 is provided with a central sleeve section 12 protruding in a direction away from the wound when the plug member 3 is positioned on the
25 outside of the vessel. A central bore 9 extends axially through the sleeve section 12 and is designed to receive the post 7 of the distal plug member 2 when the members are clamped together, as will be described below.

When pressed together, the plug members 2, 3 clamp the edge 21 of the wound in
30 the vessel between the edges of their umbrella-shaped portions 51, 52.

The central bore 9 of the proximal plug member 3 is adapted to be snap fitted onto the post 7 of the distal plug member 2. For that purpose, the bore 9 and the post 7, respectively, are provided with corresponding saw tooth profiles 10, 11. The saw
35 tooth profiles 10, 11 are so arranged that the proximal plug member 3 can be

pressed onto the post 7 of the distal plug member 2 with a force. Thereafter, the plug members can only be separated using a considerable force.

Therefore, no separate retaining means is necessary for holding the plug members
5 securely connected.

The post 7 of the distal plug member 2 has a proximally directed end surface 14. Similarly, the sleeve 12 of the proximal plug member 3 has a proximally directed end surface 13.

10

A string shaped retracting means 6, preferably a suture, is thread through the bore 8. The end of the suture 6 is prevented from passing through the bore when a tension force is applied to it with an enlarged portion. The enlarged portion could, for example, be formed by attaching a small amount of a plastic material, but the
15 simple way of providing a knot, as shown in Fig. 1 and 2, is preferred.

In order to avoid that the suture will slip out of the bore and into the vessel, subsequent to the closing of the wound as will be explained later, it should also be fixed to the bore. This could be achieved by clamping means arranged in or near the
20 bore, but it is preferred to attach the suture in the bore 8 with a small amount of an adhesive (not shown). Although adhesive alone could be used for securing the suture to the bore, the use of the knot is preferred for safety reasons.

It should be noted that although the closure plug and the retracting means
25 described above are suited for use with the tool of the invention, as will be described in the following, they could be used for closing a puncture wound in a vessel also when any other suitable insertion tool is used.

A first embodiment of an inserting tool 101 according to the invention shall now be
30 described with reference to Fig. 3 - 7. It should be noted that in order to make the figures easy to read, a complete set of referral numbers are not provided in each figure.

It is preferred to use the tool to insert a closure plug as disclosed above, but it
35 should be noted that any plug design suitable to cooperate with the inserting tool could be inserted with the tool of the invention. The reason for preferring the plug

according to the present invention is that the use of a separate retracting means, such as a suture, as will be described below provides an improved flexibility of the distal plug member 2 to adapt to the inner wall of the vessel. The use of a suture is also advantageous for performing the wiring in the gear mechanism, as will be
5 described below.

Furthermore, the use of generally umbrella-shaped plug members is advantageous in that an even pressure is applied to the wound edge, thereby reducing the risk for wound edge rupture. The disk shape of the plug members also provides improved
10 possibility to achieve a non-leaking closure. However, the present invention is adaptable for use with other types of plug members, such as those described in US patent 5,531,759.

The inserting tool should be used with an introducer 23. Any introducer being well
15 known in the field of surgical treatment through a blood vessel could be used provided that a fitting 31 of the inserting tool 101 is adapted to a corresponding fitting 26 of the introducer 23 (or is coupled with any suitable separate means, such as clamps). Also, the dimensions of the inserting tool components should be adapted to the introducer, as will be understood from the following description. In
20 Fig. 3 the skin of the patient is indicated with the referral number 24.

As is shown in Fig. 3, the inserting tool comprises an elongated casing 30 enclosing a gear mechanism 32, an outer feeding means 33, an inner feeding means 34, a proximal plug member 3, a distal plug member 2 and a suture 6 (forming a
25 retracting means). The wiring of the suture 6 through the plug members 2, 3 is clearly shown in Fig. 1 and 2.

An elongated opening 35 extends through the casing 30 in the axial direction. An insertion lever 36 extends through the opening 35. The insertion lever is slideable in
30 the opening, and is connected to the gear mechanism 32 inside the casing 30, as will be described. Therefore, when the insertion lever is pushed forward it acts as a pusher means for moving the gear mechanism.

The outer feeding means 33 has a through bore extending axially. The inner feeding
35 means 34 is inserted into the bore of the outer feeding means 33 for axial

movement. A similar through bore extends axially through the inner feeding means 34 for accommodating the suture 6 to move axially therein.

5 With reference to Fig. 4 and 5, the gear mechanism 32 comprises a pulley spacer member 37, for holding the pulley 38 at a distance from the proximal end of the bore through the outer feeding means 34. The pulley spacer member 37 is fixedly attached to the proximal end of the outer feeding means 33, and a bore (not shown) through the pulley spacer member 37 is positioned to form an extension of the bore through the outer feeding means such that the inner feeding means 34 can move
10 freely through the pulley spacer member 37. A first pulley 38 is rotatably attached to the proximal end of the pulley spacer member 37.

The gear mechanism 32 also comprises a clamping block 39, at its distal end fixedly attached to the inner feeding means 34 by means of a bore (not shown) in the
15 clamping block 39 such that the suture can move freely through the clamping block. A second pulley 40 is rotatably attached to the clamping block 39, and is substantially rotating in the same plane as the first pulley 38.

A first brake means 41, consisting of a spring-loaded brake shoe 42, is mounted on
20 the clamping block 39. A second brake means 43, consisting of a spring loaded brake shoe 44, is mounted on the interior part of the insertion lever 36.

The suture 6, having a knot in its distal end so that it does not slip through the bore of the distal plug member 2, runs through the distal plug member 2, through
25 the inner feeding means 34, out from the clamping block 39 where the suture is held in the first brake means 41, around the first pulley 38, back towards the clamping block, around the second pulley 40 to finally be held by the second brake means 43 of the insertion lever 36. The suture is stretched in order to urge the post 7 end surface 14 of the distal plug member 2 against the inner feeding means 34.

30 The proximal plug member 3 is disposed around the inner feeding means 34 to move along it, but is restricted from moving in the proximal direction by the end of the outer feeding means 33.

35 The distal end of the casing has a tapered section 45. Therefore, the mouth 46 at the distal end of the tool is more narrow than the outer diameters of the plug

members, respectively. However, due to the shape of the plug members and the flexibility of their material they will collapse if pressed through the tapered section 45 out of the mouth 46.

- 5 Before use of the tool, the gear mechanism together with all components attached thereto is withdrawn towards the proximal end of the casing 30, as shown in Fig. 3.

An embodiment of a method for closing a wound in a vessel, utilizing the embodiment of an insertion tool as described above, shall now be described.

10

In a first step of the method of the invention, as shown in Fig. 3, the insertion tool 101 is coupled to an introducer 23 being positioned in the wound in the vessel 20.

- 15 In a second step of the method of the invention, as shown in Fig. 4, the insertion tool casing 30 is held essentially stationary with respect to the wound while the insertion lever 36 is pushed towards the wound. The insertion lever 36 abuts against the clamping block 39 to push the clamping block and the pulley spacer member 37 and, consequently, the inner and the outer feeding means 33, 34 towards the wound. Thereby, the plug members 2, 3 are pressed into the tapered section 45 of the casing 30 to collapse to a diameter allowing them to be pushed through the introducer 23.
- 20

- The length of the opening 35 in which the insertion lever 36 moves, as well as the lengths of other components of the insertions tool 101, are selected to suit the length of the introducer 23 such that when the insertion lever reaches the distal end of the opening to be stopped there, the distal plug member 2 exits out of the introducer 23.
- 25

- When the distal plug member 2 exits from the introducer 23 it unfolds inside the vessel 20. Thereby, the operator is able to feel a "snap", being a signal that the distal plug member 2 is properly inserted.
- 30

- In a third step of the method of the invention, as shown in Fig. 5 and 6, the insertion tool 101 together with the introducer 23 is withdrawn from the wound with a force F_1 to mate the plug members 2, 3. During this step the distal plug member 2 abuts against the inside of the vessel wall 21 to cover the inside of the
- 35

edge of the puncture. The force F_1 should be controlled by selecting the braking force of the second brake means 43, to be low enough not to rupture the vessel wall around the puncture wound. A typical force for closing a wound in the femoralis artery, which is an artery in which surgical puncture wounds often are opened, without rupturing the vessel is 2 N.

During the withdrawal the suture is stretched around the first pulley 38 and the second pulley 40 and is held at its proximal end by the clamping force of the second brake means 43. The first brake means 41 serves to keep the clamping block 39, and consequently also the inner feeding means 34, at place with respect to the suture 6. The breaking force of the first brake means is adjusted to be the same as the breaking force of the second brake means.

The distance between the second brake means 43 and the second pulley 40 is constant since the insertion lever 36 abuts the clamping block 39. Therefore, the first pulley 38 is drawn towards the second pulley 40. In this movement, the first pulley 38 pushes the pulley spacer member 37, and consequently the outer feeding means 33 and the proximal plug member 3, towards the distal plug member 2.

The snap fitting of the plug elements is designed to require a snapping force of the same order as the force of withdrawal of the tool, that force being transferred to the proximal plug member as described above. Since the gear ratio of the gear mechanism according to the present invention is approximately unity, the plug members are mated with a force substantially the same as the force with which the tool is drawn away from the patient. The brake means 41, 43 limit this force to prevent it from being higher than the strength of the vessel. Therefore, the saw tooth profile should be designed to allow for mating of the plug members with a force somewhat less than the suture breaking force applied by the brake means.

The mating of plug members 2, 3 continues until the first pulley 38 and the pulley spacer member 37 runs into the second pulley 40 and the clamping block 39, as shown in Fig. 6.

In a fourth step of the method of the invention, as shown in Fig. 7, the insertion tool together with the introducer 23 is further withdrawn from the patient to finally remove the tool from the wound.

During this continued withdrawal of the tool casing 30 the insertion lever 36 is urged to stretch the distal suture end. The braking force of the second brake means 43 will not be able to hold the suture 6 when the withdrawing force exceeds said
5 braking force, and consequently the suture will become free from the insertion lever. Continued withdrawal of the casing 30 will result in the same effect at the first brake means 41, thereby leaving the suture free from the tool. The suture remains protruding out from the skin end of the wound, and may be cut to a proper length.

10 It should be noted that the suture acts as a force transmitting means only, and is not used for holding the plug member together after mating or for pressing any of the plug members towards the vessel wall.

15 A second embodiment of the tool of the invention 102 shall now be described with reference to Fig. 8 - 12.

As seen in Fig. 8, a casing 130, an introducer fitting 131, a tapered end section 145 of the casing 130, a mouth 146 at the distal end of the tool 102 corresponds to the
20 first embodiment described above. Also, the plug members 2, 3, the suture 6 and the outer and the inner feeding means 133, 134 are initially disposed in the casing 130 as for the first embodiment above. The outer and inner feeding means runs with a clearance through a bore 173 in the casing, said bore 173 being narrow enough to act as a guide that prevents the feeding means from excessive bending in
25 a case where they are formed from a highly flexible material, such as a thermoplastic. Such highly flexible material for forming the feeding means is advantageous in that it improves the flexibility of the feeding means, thereby providing higher freedom of movement within the wound.

30 The inserting tool 102 comprises a gear mechanism 132 of a different design than the gear mechanism 32 of the first embodiment. According to the second embodiment, the proximal end of the inner feeding means 134 is formed as a block section 160 protruding towards the viewer of Fig. 8, while the proximal end of the outer feeding means 133 is formed as a plate section 161 extending axially with
35 respect to the outer feeding means and perpendicularly with respect to the block

section 160. The block section 160 extends through an axial opening 162 in the plate section 161 to be axially movable in the opening 162.

5 The longitudinal sides of the plate section 161 of the outer feeding means 133 are provided with cog profiles 163a, 163b.

10 An upper plate 164 in which a substantially T-shaped opening 165 is formed is positioned above, and substantially parallel with, the plate section 161 such that the block section 160 extends through the "leg" of the T-opening. A wire spring 166 is biased into the T-opening, transverse to the "leg", and runs through a small hole in the block section 160 to press the upper plate 164 towards the block section 160.

15 Two double gear wheels 168a, 168b, each one having a small gear ring 180 and a large gear ring 181 (as seen in Fig. 9) being fixed with respect to each other, are rotatably mounted in the upper plate 164. The gear wheels 168a, 168b are disposed one at each side of the plate section 161 such that the small gear ring 180 of each gear wheel engages the cog profile 163a, 163b of the respective side of the plate section 161.

20 A cover 150 being axially slideable in guides 169 in the casing 130 covers the plate section 161, the upper plate 164 and their associated components, as shown in Fig. 8, 10 and 11. Two inner gear racks 170a, 170b, one at each inner side of the cover 150, runs axially inside the cover. When the cover is mounted on the casing, the large gear rings of the double gear wheels 168a, 168b are engaged with the gear racks 170a, 170b, respectively.

25 The upper plate 164 abuts against an inner seat 171 of the cover 150. When the cover 150 is pushed forward with respect to the casing 130, i.e. in a distal direction, it pushes the upper plate 164 forward as well, and brings with it the other components of the gear mechanism. Therefore, when the cover is pushed forward it acts as a pusher means for moving the gear mechanism.

30 As shown in Fig. 12, the proximal end of the suture 6 ends in a small recess in the substantially T-shaped opening 165 of the upper plate 164, and is stretched and clamped between the block section 160 of the inner feeding means 134 and the upper plate 164 by means of the wire spring 166. The bias of the wire spring is

selected to apply a suture holding force lower than the rupture pull force of the vessel. The suture holding force corresponds to the force with which the tool is drawn away from the wound during use.

- 5 It should be noted that it is possible to design a gear mechanism having one double gear wheel, cog profile and gear rack set only, if the other set is replaced by a guide means to allow for a proper linear movement. However, the embodiment being described herein with reference to Fig 8 - 17 is presently assessed to provide a more reliably performance.

10 A second embodiment of the method for closing a wound in a vessel, utilizing the second embodiment of the insertion tool 102, shall now be described with reference to Fig. 13-17.

- 15 In the first step of the second embodiment of the method of the invention, as shown in Fig. 13, the insertion tool 102 is coupled to an introducer 123 being positioned in the wound and extending through the wall of the vessel.

In the second step of the second embodiment of the method of the invention, as
20 shown in Fig. 14, the insertion tool casing 130 is held essentially stationary with respect to the wound while the cover 150 is pushed towards the wound. As described above, when pushed forward, the cover 150 brings the upper plate 164 forward as well. As both the inner and the outer feeding means 133, 134 are coupled to the upper plate they are pushed through the introducer 123 towards the
25 wound. Thereby, the plug members 2, 3 are pressed into the tapered section 145 of the casing 130 to collapse to a diameter allowing them to be pushed through the introducer 123.

The cover 150 is pushed forward (i.e. in the distal direction) until the distal plug
30 member 2 exits from the introducer 123 to unfold itself inside the vessel 20. When the distal plug member 2 unfolds this is registered by the operator as a "snap".

As for the first embodiment, the dimensions of the parts involved are selected to suit the length of the introducer 123.

In the third step of the second embodiment of the method of the invention, as shown in Fig. 15 and 16, the insertion tool 102 together with the introducer 123 is withdrawn from the wound with a force F_1 to mate the plug members 2, 3 corresponding to what has been previously described for the first embodiment.

5

However, the gear mechanism 132 of the second embodiment provides a gear ratio higher than unity, thereby enabling the plug members 2, 3 to be mated with a force higher than the withdrawing force of the tool. This shall now be described.

10 As the operator pulls the insertion tool 102 away from the wound subsequent to the unfolding of the distal plug member, the cover 150 abuts against a stopping means, such as a step-shaped edge 172 (see Fig. 12) extending from the casing 130. Therefore, as the casing 130 is pulled further away from the patient, the cover 150 follows this movement while the suture 6 remains stretched to keep the block
15 section 160 at a substantially constant distance from the distal plug member.

At the same time, the stretching force in the suture is transferred to the upper plate 164 via the block section 160. However, as the cover 150 and consequently the gear racks 170a, 170b are pushed with the force F_1 with respect to the suture, this force
20 F_1 acts on the large gear ring 181 of each gear wheel 168a, 168b, respectively, to rotate the gear wheels. Due to lever action, this creates a force F_1+F_2 in the small gear rings 180 to act on the cog profiles 163a, 163b of the plate section 161 (see Fig. 9) for driving the plate section in the opposite direction with respect to the tool pulling force, i.e. in the distal direction.

25

Thus, although the casing 130 and the cover 150 are pulled away from the distal plug member 2 with a force F_1 , the plate section 161 strives towards the distal plug member 2 with the force F_1+F_2 . As the plate section 161 moves in the distal direction, the outer feeding means 133 moves with it towards the distal plug
30 member 2.

Therefore, the proximal plug means 3 is mated with the distal plug means 2 with the force F_1+F_2 .

In the fourth step of the second embodiment of the method of the invention, as shown in Fig. 17, the tool 102 is further withdrawn from the patient to finally remove the tool from the wound.

5 During this continued withdrawal of the tool, the withdrawing force now acts on the point where the proximal end of the suture 6 is clamped between the upper plate 164 and the block section 160. When the pulling force exceeds the force of the wire spring 166 acting of the suture via the block section, the spring will loose its grip on the suture and the suture will slip out of the inner bore of the inner feeding means
10 of the tool. The suture may then be cut to a proper length.

Using the method and the tool according to the second embodiment of the invention is preferred as compared to the first embodiment since the additional mating force F_2 allows the edges of the wound to be positively clamped between the plug
15 members to ensure a safe closure of the wound even in a case where the material of the plug relaxes somewhat after insertion.

Using the tool of the present invention has many advantages.

20 No ordinary skill is required to ensure that the intra-arterial member of the closure plug is entirely inserted into the vessel, since this is taken care of by designing of the tool with suitable dimensions with respect to the introducer.

The "snap" feeling gives a positive indication to the operator that the intra-arterial
25 member of the closure plug has unfolded properly.

The entire closing procedure is performed by the simple and natural withdrawing movement of the tool from the wound. The operator only has to take care not to withdraw the tool too fast from the wound, thereby exceeding the mechanical
30 response in the gear mechanism.

There is no need for the operator to monitor a force gauge, since the brake means applied to the retracting means are preset to loosen their grip on the retracting means if an excessive withdrawing force is applied. Therefore, the risk of rupturing
35 the vessel is considerably reduced.

CLAIMS

1. A tool (101; 102) for inserting and mating two plug members (2, 3) of a sealing device (1) for closing a wound in the wall of a vessel, one plug member of the
5 sealing device being a distal plug member (2) to be positioned inside the vessel and the other plug member being a proximal plug member (3) to be positioned outside of the vessel,
and the distal plug member being provided with an elongated retracting means (6) extending from the distal plug member,
10 **characterized in** that the tool comprises
a gear mechanism (32; 132) coupled to the retracting means for converting a movement of the tool in a proximal direction away from the wound, when the distal plug member is anchored in the vessel, to a pushing movement for moving the
proximal plug member in a direction towards the distal plug member in response to
15 a stretching force (F_1) in the retracting means.
2. The tool (101; 102) according to claim 1,
characterized in that the tool comprises
a spring-biased coupling means (41; 164, 166) for releasably coupling the retracting
20 means (6) to said gear mechanism (32; 132).
3. The tool (101; 102) according to claim 2,
characterized in that the biasing force of said spring-biased coupling means (41; 164, 166) is selected to release the retracting means (6) when the stretching force
25 (F_1) in the retracting means exceeds a selected force attributed to the rupture -
tension of the wall of vessel.

- 4: The tool (101; 102) according to anyone of claims 1 through 3,
characterized in that said tool comprises
an outer feeding means (33; 133) for pushing the proximal plug member (3), said
outer feeding means being provided with an axial through bore;
5 an inner feeding means (34; 134) for pushing the distal plug member (2), said inner
feeding means being provided with an axial through bore for moveably receiving
said retracting means (6), and said inner feeding means being disposed for
movement in said bore of said outer feeding means;
said gear mechanism (32; 132) being coupled to said inner feeding means and said
10 outer feeding means; and
a pushing means (36, 150) for pushing the gear mechanism (32; 132), the outer
feeding means (33; 133) and the proximal plug member (3) with respect to the
casing (30; 130) of the tool, in a direction towards the wound.
- 15 5. The tool (102) according to claim 4
characterized in that said gear mechanism (132) comprises
at least one of a set comprising
a gear rack (170a, 170b) fixed to said pushing means (150),
a cog rail (163a, 163b) connected to said outer feeding means (133),
20 a double gear wheel (168a, 168b) having a small gear ring (180) and a large gear
ring (181) fixed with respect to each other, said double gear wheel being rotatably
connected to a plate member (164),
said large gear ring (181) being in engagement with said gear rack (170a, 170b) and
said small gear ring (180) being in engagement with said cog rail (163a, 163b),
25 and said plate member (164) being arranged to move with said outer feeding means
and said plate member releasably holding the retracting means by means of a
spring (166), the retracting means being moveably disposed in the bore of said inner
feeding means,
said set thereby cooperatively arranged to convert a proximal movement of said tool
30 to a distal movement of said outer feeding means when the retracting means is
stretched.

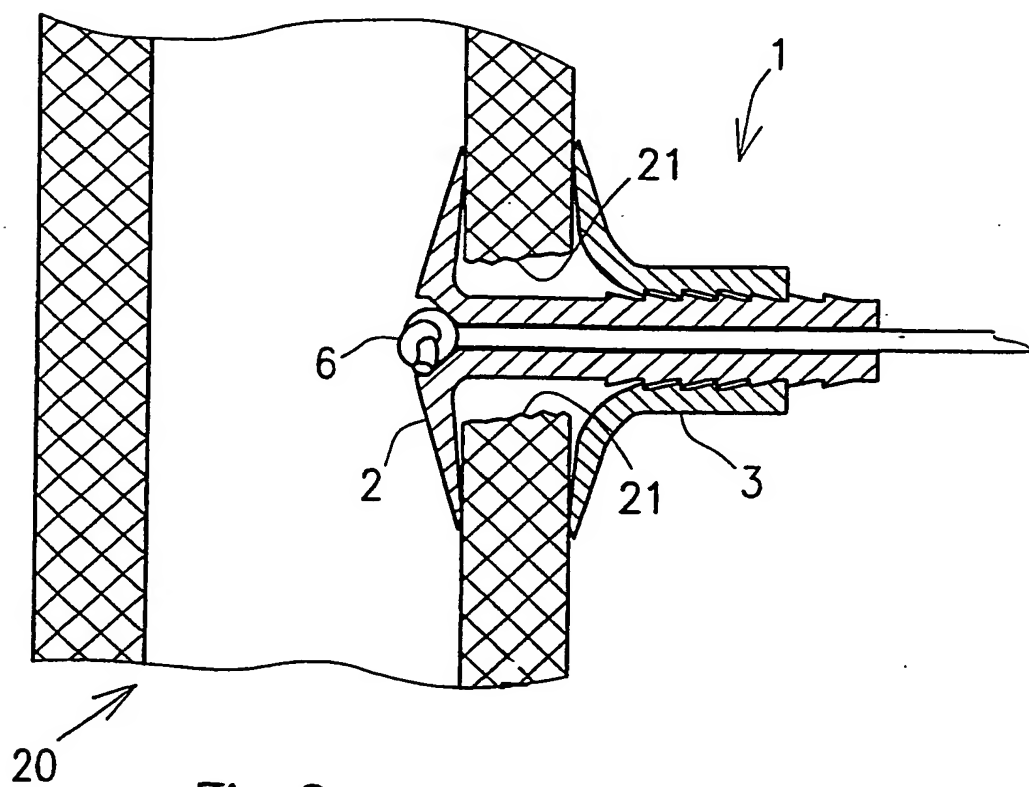
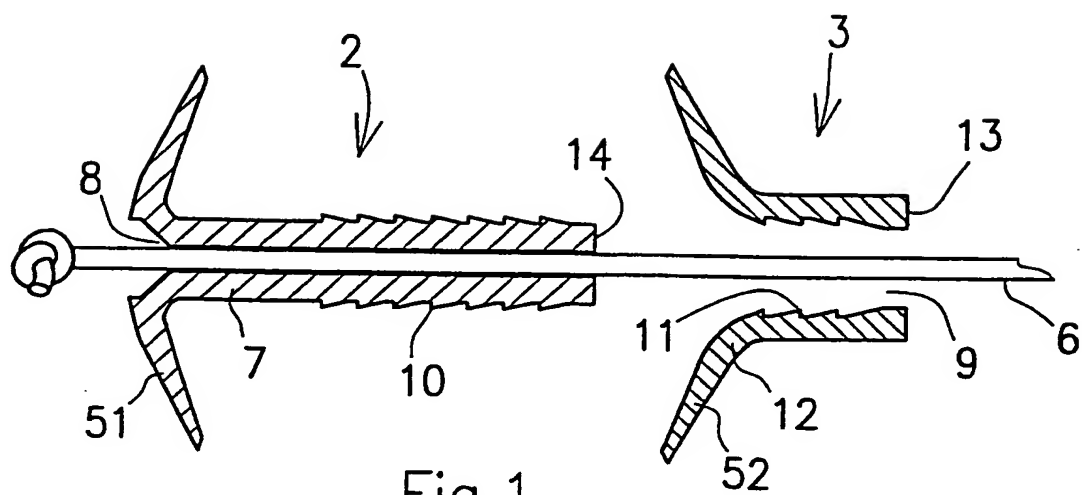
6. The tool (101) according to claim 4
characterized in that said gear mechanism (32) comprises
a first pulley (38) attached to said outer feeding means via a spacer member (37);
a second pulley (40) attached to said inner feeding means (34);
5 a first brake means (41) attached to said inner feeding means;
a second brake means (43) attached to said pushing means (36); and
wherein the retracting means (6) is arranged such that it extends from the distal
plug member (2) in a proximal direction, through said bore of said inner feeding
means (33), through the first brake means (41), around said first pulley (38) to be
10 redirected to a distal direction, around said second pulley (38) to be redirected
again to the proximal direction, and through said second brake means (43).

7. A sealing device (1) including a distal resiliently expandable plug member (2)
having an elongated retracting means extending centrally from the distal plug
15 member and including a portion (10) for attaching a proximal plug member (3) of
the sealing device, the proximal plug member being resiliently expandable and
being adapted to be mounted onto the distal plug member to be fixed thereto by
means of the attaching portion,
characterized in that the distal plug member comprises a through bore (8), and a
20 suture (6) is passed through said bore (8) to serve as the retracting means by
providing an enlarged portion at one end as a counter when pulling the suture.

8. A system for closing a wound in a punctured vessel,
characterized in that a sealing device according to claim 7 is inserted and mated
25 by the use of a tool according to anyone of claims 1 through 6.

9. A method for closing a wound in a punctured vessel by inserting and mating two plug members (2, 3) of a sealing device (1), one plug member of the sealing device being a distal plug member (2) to be positioned inside the vessel and the other plug member being a proximal plug member (3) to be positioned outside of the vessel, and the distal plug member being provided with an elongated retracting means (6) extending from the distal plug member, the method including the step of
- positioning the distal plug member (2) inside the vessel with the retracting means (6) being attachable to the tool;
- 10 characterized in that it comprises the steps of
- providing a tool (101; 102) comprising a gear mechanism (32; 132) connectable to the retracting means for converting a movement of the tool in a proximal direction away from the wound, to a pushing movement for moving the proximal plug member in a direction towards the distal plug member in response to a stretching force (F_1) in the retracting means when the distal plug member is anchored in the vessel; and
 - withdrawing the tool (101; 102) with the retracting means attached thereto to stretch the retracting means, thereby activating the gear mechanism to approach the proximal plug member towards the distal plug member via a feeding means (34; 134).
10. The method according to claim 9, wherein said tool (101; 102) comprises a spring-biased coupling means (41; 164, 166) for releasably coupling the retracting means (6) to said gear mechanism (32; 132).

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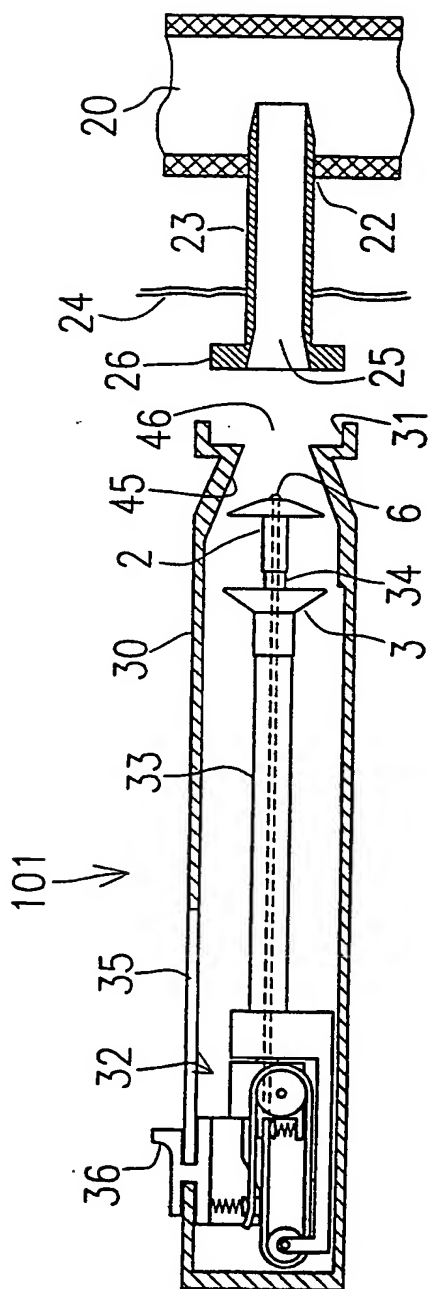


Fig. 3

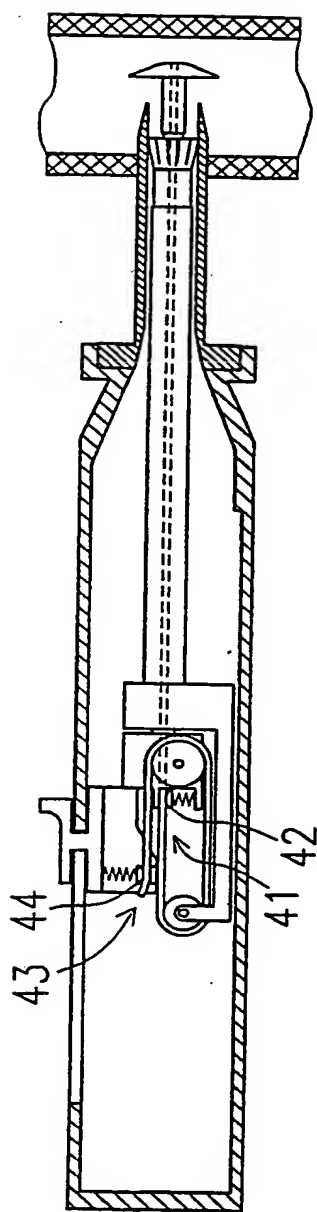


Fig. 4

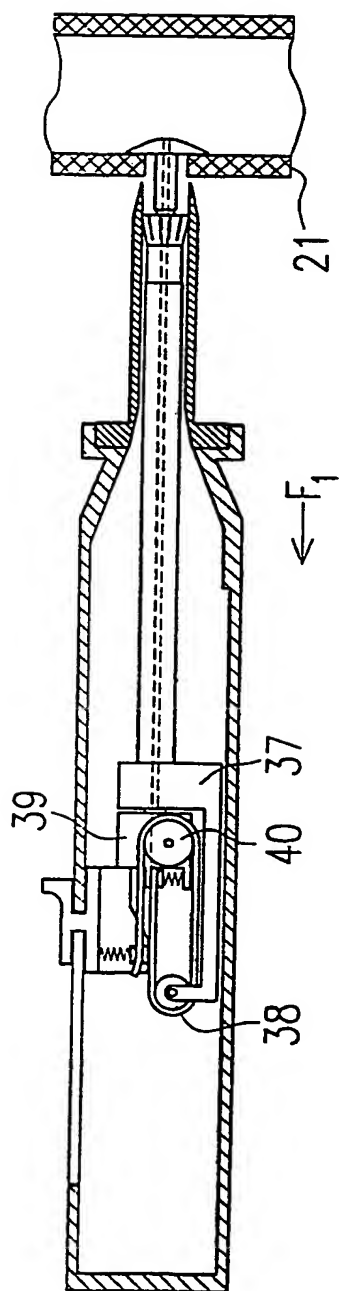


Fig. 5

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Fig. 6

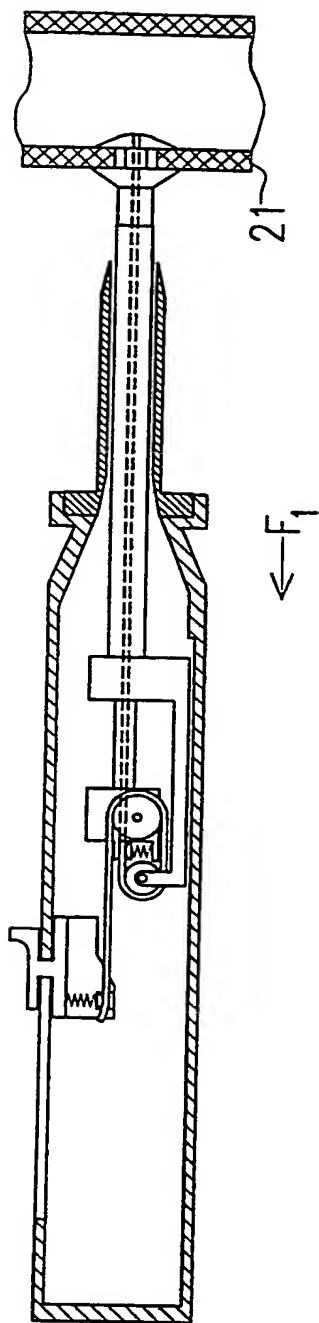
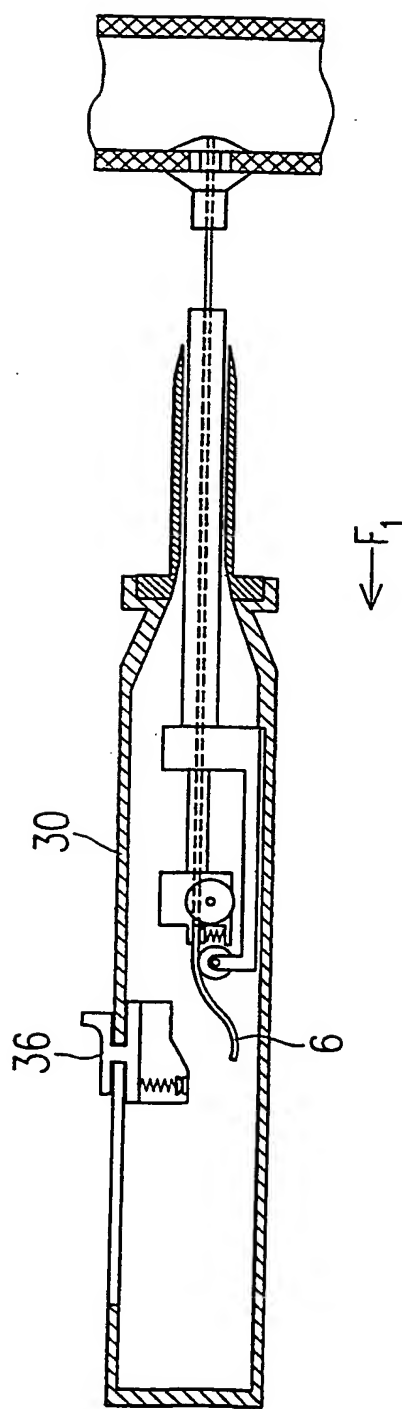


Fig. 7



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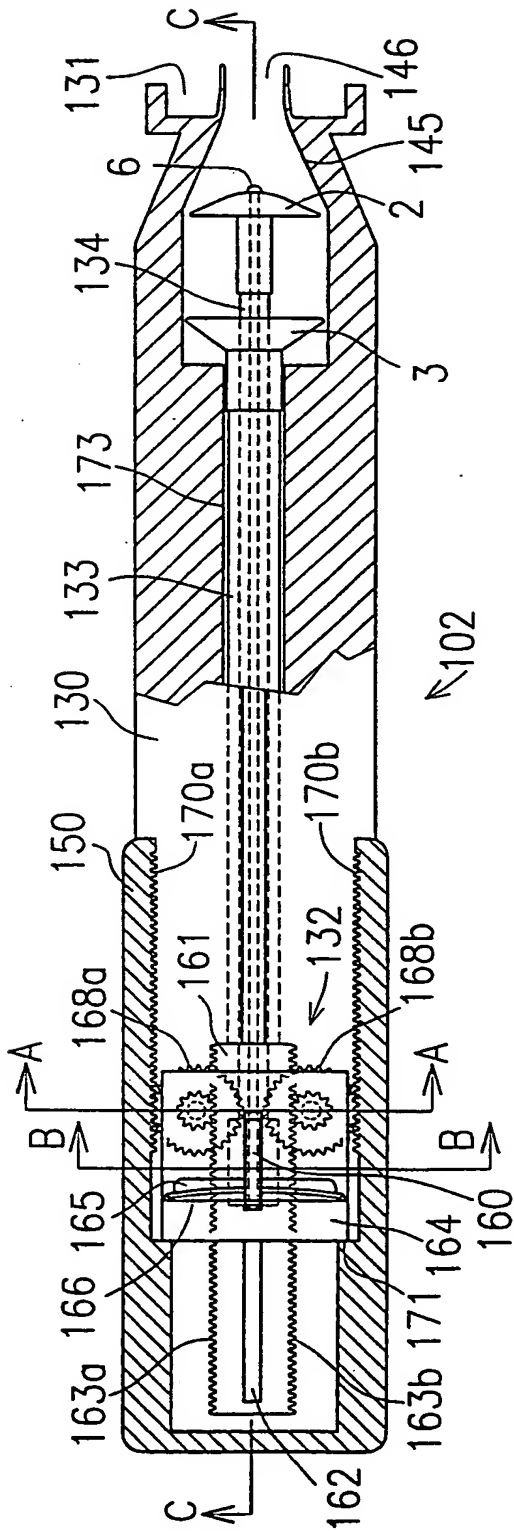


Fig. 8

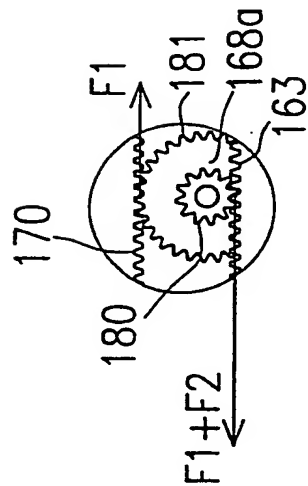


Fig. 9

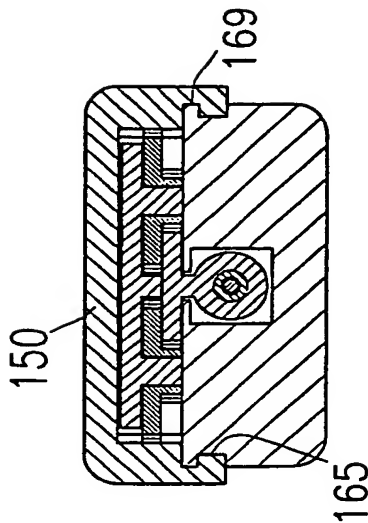


Fig. 10

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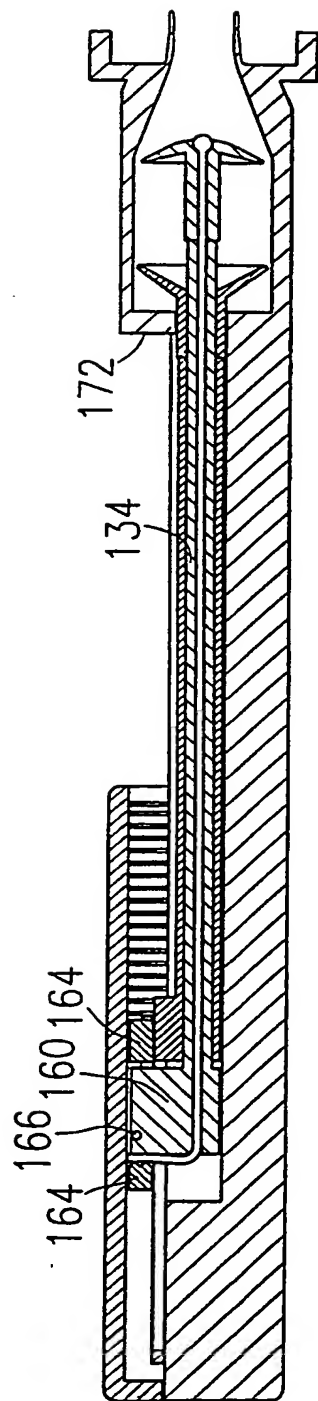


Fig. 12

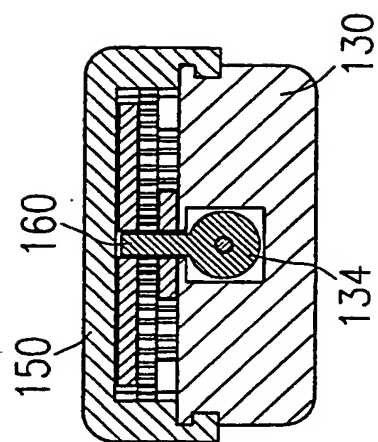
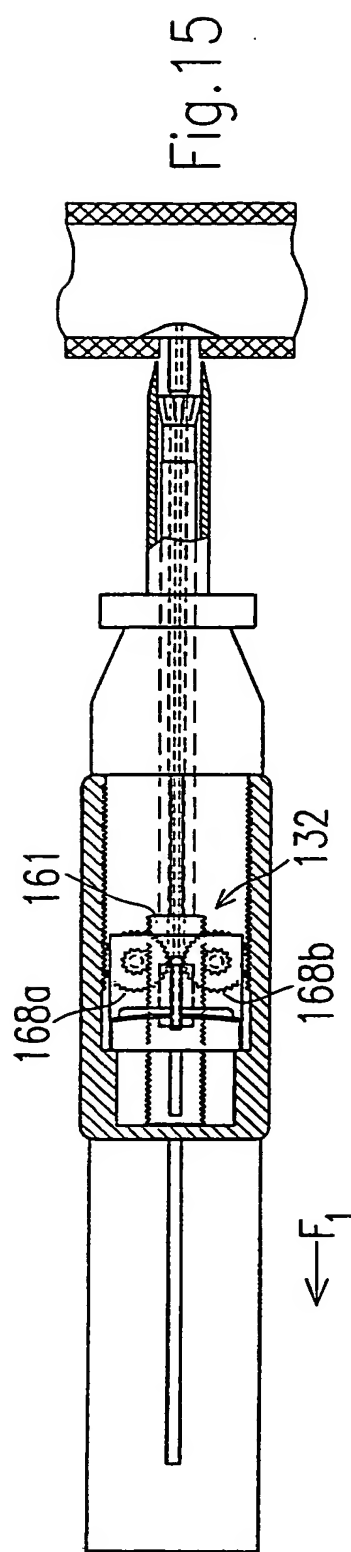
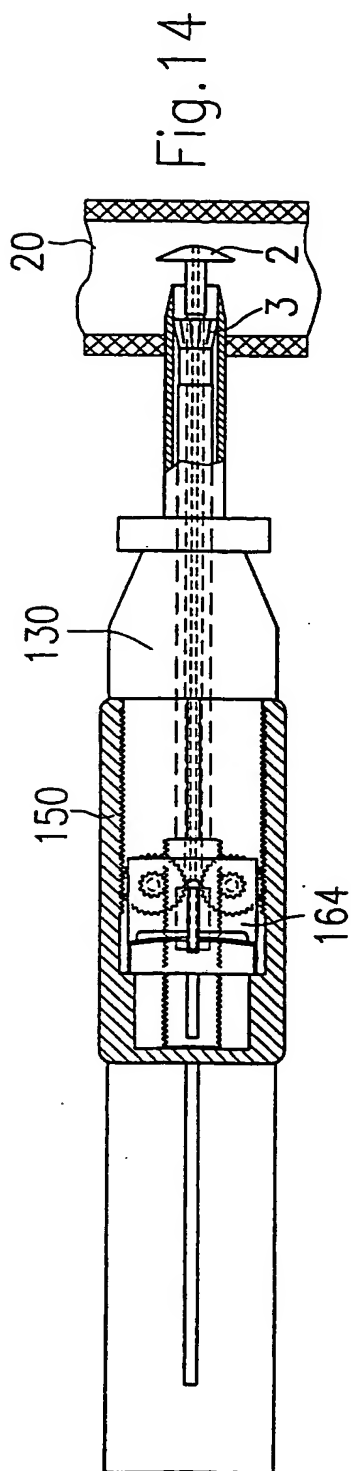
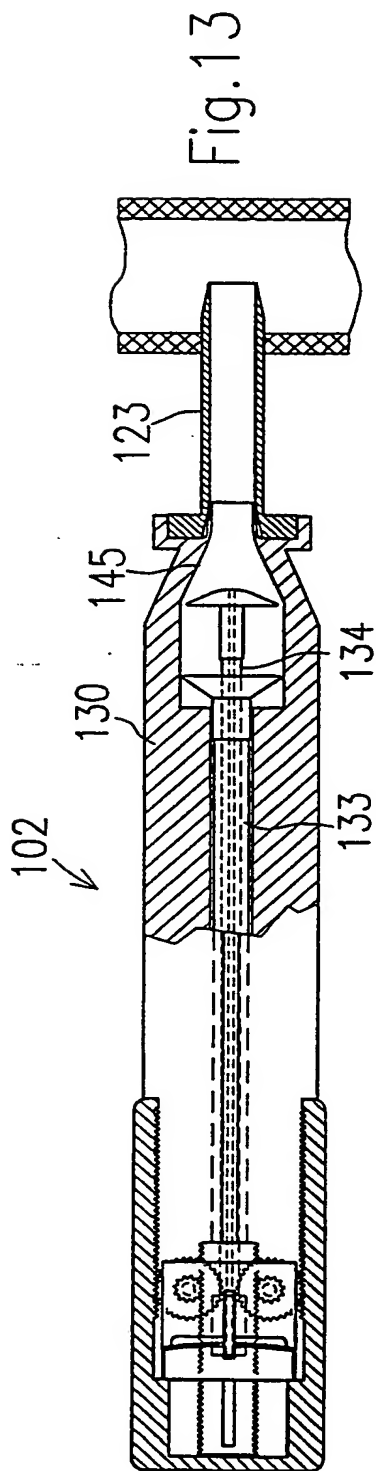
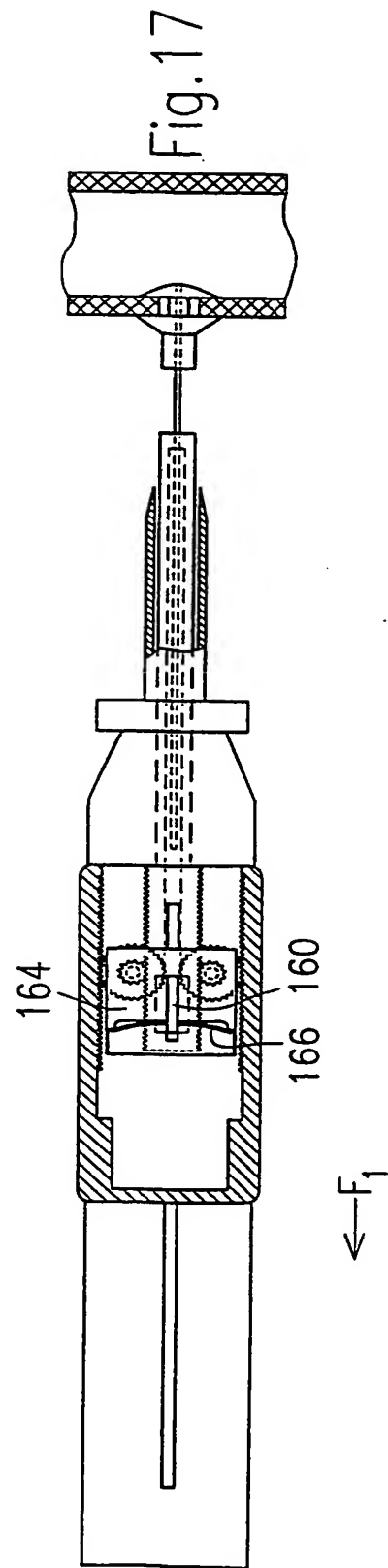
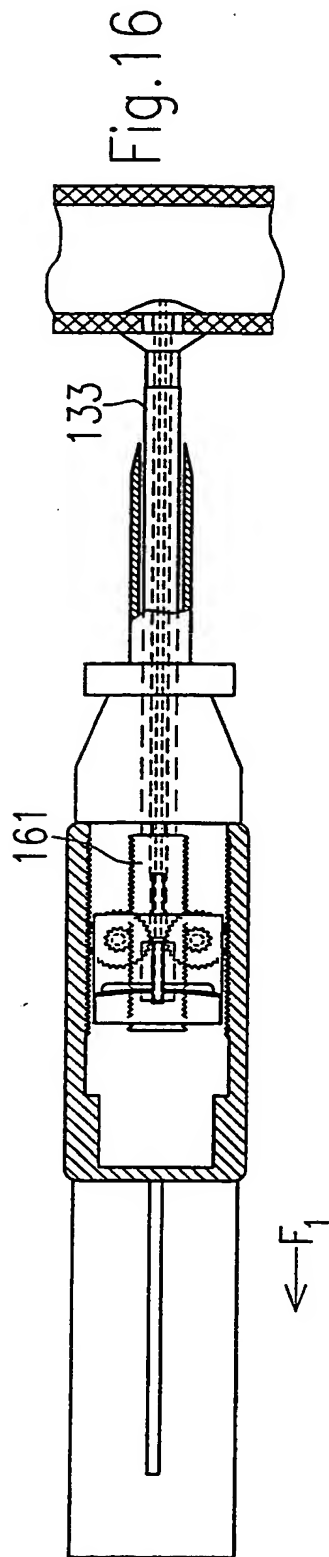


Fig. 11

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01114

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5342393 A (STACK), 30 August 1994 (30.08.94), column 2, line 25 - column 4, line 22	7,8
A	--	1-6
Y	US 5350399 A (ERLEBACHER ET AL), 27 Sept 1994 (27.09.94), column 5, line 30 - column 8, line 65	7,8
A	--	1-6
Y	US 5531759 A (KENSEY ET AL), 2 July 1996 (02.07.96), column 6, line 47 - column 8, line 15	7,8
A	-- -----	1-6

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

9 February 2000

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INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.
PCT/SE 99/01114

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
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US	5350399	A	27/09/94	CA 2078530 A EP 0534696 A JP 5212038 A	24/03/93 31/03/93 24/08/93
US	5531759	A	02/07/96	AU 2462095 A CA 2188751 A EP 0759725 A JP 9512461 T US 5545178 A WO 9529635 A	29/11/95 09/11/95 05/03/97 16/12/97 13/08/96 09/11/95